UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,059	05/28/2002	Henry Yue	PF-0681 USN	4670

22428 7590 08/18/2006

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
WEGERT, SANDRA L	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,059	YUE ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Response filed 23 May 2006 has been entered. Claims 1-23 are cancelled by the Applicant (23 May 2006). Claims 24-34 are new and read on the elected polynucleotide Invention.

Claims 24-34 are pending in this Office Action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections/Objections

Title

The objection to the title for being overly vague is *withdrawn* due to Applicants arguments (23 May 2006).

URL's

The objection to the Specification because it contained browser-executable code, is *withdrawn*. Applicants amended the Specification to remove all URL's (23 May 2006).

Claim Objections

The objection to Claims 4 and 10 for reciting non-elected inventions is *withdrawn*. Applicant cancelled Claims 4 and 10. New Claims do not recited non-elected inventions (23 May 2006).

The objection to Claims 3 and 8 for depending from withdrawn (non-examined) independent claims, is *withdrawn*. Applicants cancelled Claims 3 and 8 (23 May 2006).

New or Maintained Rejections/Objections

35 U.S.C. § 101/112, first paragraph-, Lack of Utility, Enablement.

Claims 24-34 are rejected under 35 U.S.C. 101, as lacking utility. The reasons for this rejection under *35 U.S.C. § 101* are set forth at pp. 3-9 of the previous Office Action (23 January 2006). Claims 24-34 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth in the previous Office Action (23 January 2006), one skilled in the art clearly would not know how to use the claimed invention.

Applicants argue (23 May 2006, pages 5- 11 and throughout) that the results presented in the instant Specification are enabling for the nucleic acid of SEQ ID NO: 57 encoding the polypeptide of SEQ ID NO: 28. They argue that the "human transmembrane protein" or *HTMP* contains recognizable protein motifs, such as a leucine zipper, a signal peptide and a transmembrane motif (Table 2, Specification). They also point out that the *HTMP* is expressed in a variety of tissues (data not shown) of which 40% were gastrointestinal and 20% were reproductive tissues. Applicants also point to the number and kinds of diseases possible in such tissues (23 May 2006, p. 8).

Applicants argue that the Specification discloses the structural features of the *HTMP*.

They point to such features as leucine zipper motifs, a signal peptide, and transmembrane domains (Table 2, Specification), thus conferring a function to the HTMP protein.

Applicant's arguments, filed 23 May 2006, have been fully considered but are not persuasive for the following reasons:

As pointed out in the previous Office Action (23 January 2006, page 7 and throughout) very little information is given in the instant Specification about a *specific* function for the HTMP protein. Furthermore, the protein has not even been properly identified. The Specification lists a variety of families of proteins and long lists of diseases that might be associated with those families (for example, pages 36-37). However, based on sequence searches, the claimed HTMP nucleic acid is probably not a member of any of the protein families listed in the Specification. Furthermore, as presented by Applicants, there are a large number of widely-varying utilities just within one family of proteins. Similarly, the Applicants suggest several possible utilities that may be attributable to the HTMP protein (Response, page 8), thus arguing against a *specific* function for this protein, or for that matter, any unknown polypeptide.

In addition, structural characteristics alone are insufficient for assigning a function to a new protein, even if well-documented. This is illustrated by Hufton, et al (1995, Biochem. J. 311: 353-366) who states that these three highly-homologous oxidases have very different functions within the cells they occupy (Table 1, for example). Furthermore, even the structural features that Applicants contend define their HTMP protein are heterogeneously-distributed across many kinds of molecules (Alberts, 1994, et al, p.p. 412-413).

Applicants further argue (Response, p. 9, 23 May 2006) that the disclosed HTMP sequence (SEQ ID NO: 28) could "be used to detect cancerous, inflamed or aberrantly

proliferative gastrointestinal and reproductive tissues (e.g, tissue typing may be performed), whereupon appropriate treatment to alleviate such symptoms could begin".

Applicant's arguments, filed 23 May 2006, have been fully considered but are not persuasive for the following reasons:

As discussed in the previous Office Action, (23 January 2006, page 13) proposed utilities, while perhaps easy to perform, and use methods that are art-recognized (such as a making antibodies and using them to detect the protein), are not *specific*. The fact that the methods suggested *could* be performed with any polynucleotide encoding a novel polypeptide, means that the proposed utilities are not specific and therefore not useful in imparting specific and substantial functions to the disclosed HTMP protein. For example, it would indeed be useful to identify diseases associated with the disclosed HTMP protein, but Applicant has provided no nexus between the HTMP and any disease. As discussed above, and in the previous Office Action (23 January 2006, page 6), significant experimentation would be required of the skilled artisan to specifically characterize the protein and search for possible diseases caused by mutation of the HTMP protein. In addition, it is not useful to generate antibodies to search for a protein for which the function is unknown.

Applicants also argue that the HTMP message was detected in gastrointestinal and reproductive tissues and that this fact imparts a diagnostic function, such as tissue-typing (Response, page 9).

Applicant's arguments (23 May 2006) have been fully considered but are not found to be persuasive for the following reasons:

In the instant case, the Specification suggests that the peptide may be expressed in an unknown number of gastrointestinal and reproductive tissues, but it gives no *specific* or *substantial* information about the disclosed peptide or claimed nucleic acid. There is no evidence regarding whether or not the HTMP polypeptide has a specific function in an organism, aside from its expression in some gastrointestinal and reproductive tissues. Applicants refer to the fact that 40% of the tissues were gastrointestinal and 20% were reproductive, however this gives no specific or substantial information about the disclosed peptide or claimed polynucleotide. Additionally, using a gene to identify a tissue is not considered a specific or substantial utility, since any gene expressed by a tissue could be used in such a manner.

Further research needs to be done to determine whether the expression of HTMP supports a role for the peptide in any tissue; such a role has not been suggested by the instant disclosure. Such further research requirements make it clear that the asserted utility is not yet in currently available form, i.e., it is not substantial. This further experimentation is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. As discussed in Brenner v. Manson, (1966, 383 U.S. 519, 148 USPQ 689), the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and,
>
> "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Accordingly, the Specification's assertions that the claimed HTMP polypeptide is overexpressed in some gastrointestinal and reproductive tissues is not substantial. Utility

requires that the skilled artisan be able to use the claimed invention at the time of filing. The specification does not provide a specific and substantial or a well-established use. A utility of being overexpressed in poorly-characterized tissues is a utility that requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use. This is not a substantial utility. Applicants have provided no indication of a condition caused by a mutant version of this polypeptide, or any conditions treated by adding this polypeptide. The only thing Applicants teach is that related genes are more highly expressed in some tissues. Without more specifics about the claimed species of polypeptide such as the types of tissues that **should** be studied as well as other questions about underlying mechanisms, the Specification has not provided the invention in a form readily usable by the skilled artisan.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation required to determine how to use the claimed polynucleotide or disclosed polypeptide in a unique and specific way, the lack of direction or guidance in the specification regarding the same, the lack of working examples that use the HTMP protein in a specific way, the state of the art which demonstrates a heterogeneity of function even among closely-related family members, and the breadth of the claims which embrace numerous HTMP proteins --undue experimentation would be required of the skilled artisan to make and use the claimed invention.

35 USC § 112, first paragraph - Written Description.

Claims 24, 27-30 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The reasons for this rejection under 35 U.S.C. § 112, first paragraph, are set forth at pp. 10-12 of the previous Office Action (23 January 2006). New Claims 24, 27-30 and 33 contain references to nucleic acids encoding proteins having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 28. Applicants were not in possession of all or a significant number of polynucleotides encoding polypeptides that have 95% homology to SEQ ID NO: 28 that still retain the function of SEQ ID NO: 28.

Applicants discuss the legal standards applied when evaluating Written Description. The examiner takes no issue with the discussion of general requirements for evaluating Written Description in this case or with the fact that Applicants are indeed in possession of SEQ ID NO: 28 in this Application. However, Applicants have not described or shown possession of all polypeptides 95% homologous to SEQ ID NO: 28, *that are functionally equivalent to SEQ ID NO: 28*. Nor have Applicants described a representative number of species that have 95% homology to SEQ ID NO: 28, such that it is clear that they were in possession of a genus of polypeptides functionally similar to SEQ ID NO: 28.

Applicants also discuss the fact that an amino acid sequence can be encoded by a variety of codons (page 13, 23 May 2006) implying that there is adequate written description of what is claimed in the instant application. They cite Appellants arguments and the CAFC's introductory comments from a case recently before the Federal Circuit (*In re Wallach*, 378 F3d 1330, 71 USPQ2d 1939 (Fed. Cir. 2004)). The examiner agrees that, if one full polypeptide is disclosed in an application, the applicant presenting that peptide is in possession of all possible DNA's

encoding that peptide. However, In re Wallach presented very different data. They had disclosed only a partial sequence of a polypeptide and were then making a claim to all the nucleic acids that encoded the *full-length* polypeptide. Furthermore, the Federal Circuit answered this question in the **negative**. The court ruled that the written description requirement for claims to the DNA molecules was **not** satisfied by disclosure of a partial amino acid sequence of the encoded protein. Given the very different fact patterns and that the case cited was answered in the negative, In re Wallach does not appear to support the Applicant's arguments.

As discussed in the previous Office Action (23 January 2006) even a very skilled artisan could not envision the detailed chemical structure of all or a significant number of encompassed HTMP polynucleotides encoding polypeptides, and therefore, would not know how to make or use them. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. The claimed product itself is required. Recitation of the phrase "wherein said polypeptide is a transmembrane protein..." (New claims, 23 May 2006), is not adequate to describe the HTMP polypeptides or the polynucleotides encoding the HTMP polypeptides, that have 95% homology to SEQ ID NO: 28, since there was no reduction to practice to support the amended claims. Applicants made no variant polynucleotides or polypeptides, and as recited in the current Written Description Guidelines, Applicants must have invented the subject matter that is claimed and must be in "possession" of the claimed genus (Federal Register, 2001, Vol. 66, No. 4, pages 1099-1111, esp. page 1104, 3rd column).

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites "a polynucleotide of SEQ ID NO 57," which encompasses sequence(s) that are indefinite as to length (e.g., it reads on short fragments of SEQ ID NO: 57, including single codons). Amending the claim to recite "the polynucleotide of SEQ ID NO 57" would overcome this rejection.

Conclusion

Claims 24-34 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW
8 August 2006

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER